

OCT 20 2004 PREMARKET NOTIFICATION [510(k)] Summary

Trade Name: SonoScape Ultrasound System, SSI-1000/SSI-5000™
with PA2.5 MHz Phased Array, LA7.5 MHz Linear Array, and
CLA3.5 MHz Curved Linear Array.

Common Name: Diagnostic Ultrasound System

Classification Name: Ultrasonic Pulsed Echo Imaging System, 90 IYO

Manufacturer's Name: SonoScape Company Limited

4/F., Yizhe Building, Yuquan Road,
Nanshan, 518051, Shenzhen, China

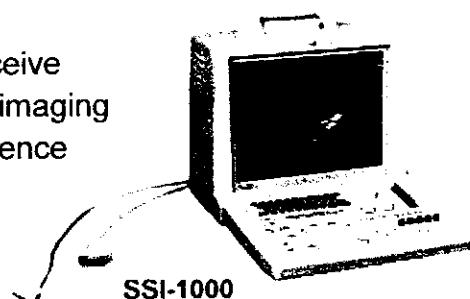
Contact: Mr. Jinzhong Yao, President
Telephone: (86) 755-26722890
Fax: (86) 755-26722850

U.S. Agent: Bob Leiker
Quality & Regulatory Services, Inc.
Dublin, CA 94568

Predicate Device: GE Logiq 500 - K970901, K991611, and K010329

Device Description: The SonoScape SSI-1000/SSI-5000 ultrasound system is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

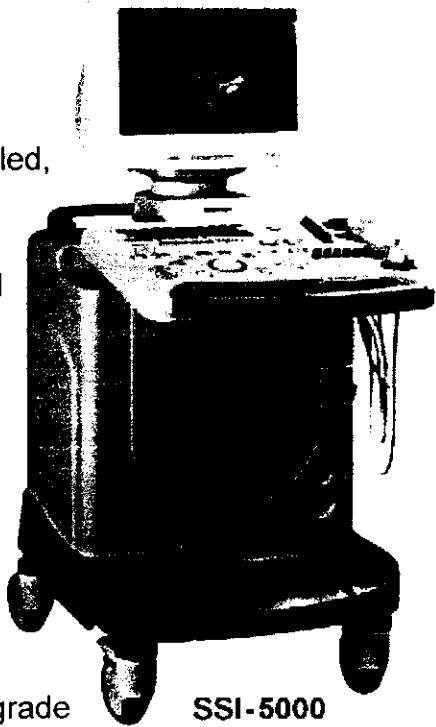


The SonoScape System can be configured either as a portable (SSI-1000) model, or as a roll-around model on wheels (SSI-5000). These systems are designed with the latest technology, using the same quality procedures as ultrasound systems which have been available in the market for years.

This SonoScape system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes.

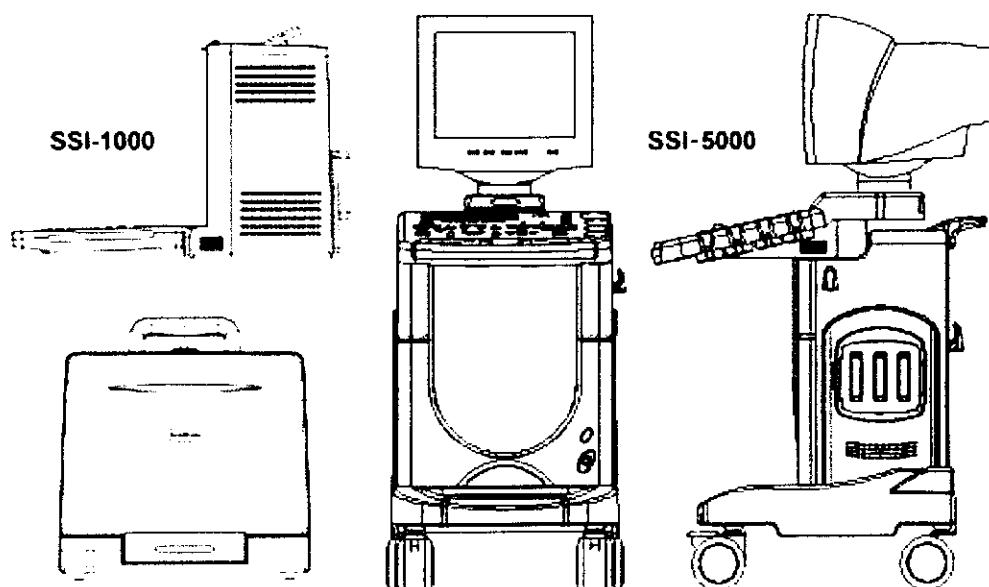
The major features of the SonoScape SSI-1000/SSI-5000:

- 64 Channel all digital beam former
- Progressive dynamic receive focusing
- Wide band all digital demodulation
- Native frequency digital scan converter
- SSI-1000 can be hand carried for portable use
- Remote access image management through LAN port
- USB2.0 flash drive for image transport and software upgrade
- Support for Phase array, Linear array, and Curve Linear array probes
- Based on Linux operating system
- Supports 2D B-mode, M-mode, Harmonic Image, Color, Power Doppler, Pulse wave Doppler, and CW.



SSI-5000

The SSI-1000 utilizes an LCD viewing monitor, and the SSI-5000 uses a CRT monitor. The following drawings are provided for illustration;



Intended Use: The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen; Pediatric; Small Organ (breast, tests, thyroid); heart soft tissue; Peripheral Vascular, Musculo-skeletal (conventional) and Urology.

Technological Characteristics

| | |
|-------------------------------|--|
| Display Modes | Single and dual 2-D; Display of Duplex 2-D/M-mode; 2-D/Pulsed Doppler and Triplex 2-D/CD/Pulsed Doppler image formats; Dual B and Color in real time |
| Measurements | Distance; area; circumference; calipers; velocity, PI, RI, Cardiac, OB and Vascular package |
| Principle of Operation | Applying high voltage burst to the Piezoelectric material in the transducer and detect the reflected echo to construct the 2-D B-mode, Doppler color, and Doppler spectrum image for diagnostic purpose. |
| Operating Controls | <ul style="list-style-type: none"> • TGC 8 slider, +/- 24dB • Depth Range: 3 to 24 cm • Image sector size: 32 lines to full B (256 lines) • Image Sector position: Steering within full maximum • B orientation flip: L/R key with marking on the screen • B Dynamic range control: preset 5 curves over 50-90 dB • Gray Scale Control: 8 Settings • Focal Number: 16 focal zone setting • B persistence: 30-90% recursive • Image Processing: Smoothing, edge enhancement • PW sweeping speed 2,4,8 sec over display. • PW Wall filter setting: 16 settings, 0.25 to 20% of PRF • PW sample volume: 0.5 to 10mm with 0.5mm step size. • PW/B update: with UPDATE key • PW cursor steering: Steer soft key • PW angle correction: 0 to 70 degree user control • PW trace: Peak, Mean • PW spectrum dynamic range: 5 preset curve over 15-48 dB • Spectrum baseline shift and invert • Color ROI setting: trackball and set key to control size and position • Color steering on flat probe: +, 0, - • Color Wall Filter: Color wall filter with 16 selection, 0.25-20% of PRF • Color & B priority: C-B priority soft menu • Color Packet size: preset per Exam range from 8 to 12 • Color spatial filter: preset per Exam, horizontal, vertical, off • Zoom factor: 1 to 10 continuously • Freeze control: Toggling freeze key • Cine control: step, play backward, play continuously |
| Acoustic Output | Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm ² maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm ² max |
| Safety Compliance | IEC601-1 International Electrotechnical Commission; Medical Electrical Equipment IEC60601-2 International Electrotechnical Commission; Electromagnetic Compatibility |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 20 2004

SonoScape Company, Ltd.
c/o Mr. Bob Leiker
Quality & Regulatory Services
7263 Cronin Circle
DUBLIN CA 94568-2330

Re: K042369

Trade Name: SonoScape SSI-1000/SSI-5000 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: October 11, 2004

Received: October 12, 2004

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoScape SSI-1000/SSI-5000 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

2P1, PA2.5 MHz Phased Array

L741, LA7.5 MHz Linear Array

C344, CLA3.5 MHz Curved Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: SonoScape SSI-1000/SSI-5000
 Diagnostic Ultrasound Pulsed Echo System
 Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|---------------------------------------|-------------------|---|---|-----|-----|---------------|---------------------------|------------------------|----------|-------------------------|
| | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined | Tissue Harmonic Imaging |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | N | N | N | | N | N | | Note 1 | N |
| Ob/GYN | | N | N | N | | N | N | | Note 1 | N |
| IntraOperative | | | | | | | | | | |
| Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (breast, thyroid, testes) | | N | N | N | | N | N | | Note 1 | N |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | N | N | N | N | N | N | | Note 1 | N |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral Vascular | | N | N | N | | N | N | | Note 1 | N |
| Laparoscopic | | | | | | | | | | |
| Muscular-Skeletal | | N | N | N | | N | N | | Note 1 | N |
| Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary C. Bragon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

Section 4.3

Indications For Use 510(k) Number _____

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Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: 2P1, PA2.5 MHz Phased Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|---------------------------------------|-------------------|---|---|-----|-----|---------------|---------------------------|------------------------|----------|-------------------------|
| | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined | Tissue Harmonic Imaging |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Ob/GYN | | | | | | | | | | |
| IntraOperative | | | | | | | | | | |
| Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (breast, thyroid, testes) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | N | N | N | N | N | N | | | Note 1 | N |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042369

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: L741, LA7.5 MHz Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

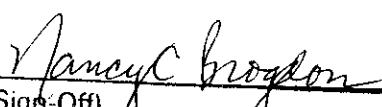
| Clinical Application | Mode of Operation | | | | | | | | | |
|---------------------------------------|-------------------|---|---|-----|-----|---------------|---------------------------|------------------------|----------|-------------------------|
| | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined | Tissue Harmonic Imaging |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Ob/GYN | | | | | | | | | | |
| IntraOperative | | | | | | | | | | |
| Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (breast, thyroid, testes) | N | N | N | | | N | N | | Note 1 | N |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral Vascular | N | N | N | | | N | N | | Note 1 | N |
| Laparoscopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | N | N | N | | | N | N | | Note 1 | N |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

Concurrence of CDRH, Office of Device Evaluation (ODE)


 Nancy C. Brogdon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

Section 4.3

Indications For Use

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Diagnostic Ultrasound System Indications for Use

510(k) Number: _____

Device Name: C344, CLA3.5 MHz Curved Linear Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|---------------------------------------|-------------------|---|---|-----|-----|---------------|---------------------------|------------------------|----------|-------------------------|
| | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined | Tissue Harmonic Imaging |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | N | N | N | | | N | N | | Note 1 | N |
| Ob/GYN | N | N | N | | | N | N | | Note 1 | N |
| IntraOperative | | | | | | | | | | |
| Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (breast, thyroid, testes) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

N = new indication P = previously cleared by FDA E = added under Appendix E

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Additional Comments:

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510(k) Number K042369

Prescription Use (Per 21 CFR 801.109)